

on **Vaccine Research** *the third annual conference*
— april 30 - may 2, 2000 / renaissance washington hotel / washington, dc

Program Abstract

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Sunday, April 30, 2000

Keynote Address

Vaccines: Seizing the Moment
William H. Foege, M.D.
Emory University

Mary Lou Clements-Mann Memorial Lecture in Vaccine Sciences

The Promise of 21st Century Science: Goals for the Global Alliance for Vaccines and Immunization
Sir Gustav Nossal
University of Melbourne

Symposium 1: The Economics of Vaccines: Industry-Public Health Interface

- The World Bank Perspective
Amie E. Batson, M.B.A.
The World Bank
- The Industry Perspective
Michel De Wilde, Ph.D. Aventis Pasteur

Submitted Presentations 1: Assessing Immunologic Response and Disease Protection

- A single additional dose of hepatitis B vaccine is enough for children who are not protected after 3 doses
Presenting Author: Bernard Duval, M.D.
CHUL Research Centre
- Would a single large dose of hepatitis B vaccine be sufficient for high risk young adults?
Presenting Author: Simon R. Dobson, M.D.
B.C. Children's Hospital
- An Inactivated Influenza Vaccine Produced from an MDCK-derived Cell Line is Safe and

Presenting Author: Isaias Raw, Ph.D.
Instituto Butantan

- Optimization and evaluation of Nabi-StaphVAX®, a Staphylococcus aureus bivalent glycoconjugate vaccine, in hemodialysis patients

Presenting Author: Ali Fattom, Ph.D.
Nabi

- First Clinical Investigation of New Lipopolysaccharides: Phase I-II Clinical Trials of Shigellae sonnei LPS Vaccines

Presenting Author: Petr G. Aparin
National Research Center—Institute of Immunology

Submitted Presentations 4: Vaccine Associated Reactions, Vaccine Safety, and Vaccine Acceptance

- Possible Role of Cell-mediated Immunity in Injection Site Reactions to a Second Booster Dose of an Acellular Pertussis-based Combination Vaccine

Presenting Author: David W. Scheifele, M.D.
BC Children's Hospital

- Safety, tolerability, and immunogenicity of varying doses of influenza vaccine administered by jet injector (JI) vs. needle and syringe (N&S)

Presenting Author: Lisa A. Jackson, M.D.
Center for Health Studies/Group Health

- Pertussis Vaccination and Risk of Asthma in Childhood

Presenting Author: Piotr Kramarz, M.D.
Centers for Disease Control and Prevention

- Demographic and Clinical Features of Patients Developing Myositis Following Immunizations

Presenting Author: Ejaz A. Shamim, M.D.
CBER/FDA

- Evaluation of transmission risks of avian leukosis virus and endogenous avian retrovirus to recipient of chick-cell-derived reverse transcriptase-positive MMR vaccine

Presenting Author: Althaf I. Hussain, Ph.D.
Centers for Disease Control and Prevention

- Should we worry that some nurses no longer fully support immunization?

Presenting Author: Bernard Duval, M.D.
CHUL Research Centre

Submitted Presentations 5: Immunomodulators and Adjuvants

- CpG ODN is safe and highly effective in humans as adjuvant to HBV vaccine: Preliminary results of Phase I trial with CpG ODN 7909

Presenting Author: Heather L. Davis, Ph.D.
Loeb Research Institute, University of Ottawa

Search CAHR Abstracts**IMPROVED HEPATITIS B VACCINE RESPONSE WITH CpG ODN 7909 ADJUVANT**

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¹Division of Infectious Diseases, Ottawa Hospital (General Campus); ²Coley Pharmaceutical Group, Wellesley, MA, USA; ³Loeb Health Research Institute, Ottawa, Canada; ⁴University of Ottawa; ⁵University of Iowa; ⁶Gastroenterology, Toronto Western Hospital, Toronto

Background: The development of safe and potent Th-1 adjuvants is a necessary step in HIV vaccine development. Immunostimulatory CpG motifs are unmethylated cytosine-guanine dinucleotides with certain flanking sequences that are common in bacterial DNA but rare in mammalian DNA. In animal models, CpG-containing oligodeoxynucleotides (CpG ODN) act as potent Th1-like adjuvants with many antigens. CpG 7909, a 24-mer ODN containing 3 CpG motifs, strongly activates human cells in vitro.

Methods: In a double-blind phase I study, healthy volunteers aged 18-35 years have been vaccinated at 0, 1 and 6 mos by IM injection with Enderix-B® (SmithKline Beecham), which contains 20 µg yeast-derived hepatitis B surface antigen [HBsAg] adsorbed to alum, with or without CpG 7909 (125, 500, 1000 µg).

Results: Interim group-wise comparison shows experimental vaccines, like control vaccines, to be generally well tolerated, both locally and systemically. HBsAg-specific antibody responses (anti-HBs) are significantly better in CpG than control subjects for all three doses of CpG tested. No control (n=12) seroconverted (SC, anti-HBs > 1 mIU/ml) at 2 wk post-prime. There was 17% SC and 8% seroprotection (SP, > 10 mIU/ml) by 4 wk. In contrast, CpG 7909 (500 µg) recipients (n=11-12) had 82% and 92% SC and 55% and 75% SP at 2 and 4 wk. Post-boost (6 wk), SP was 55% for control subjects but 100% for CpG 7909 recipients (n=35). Anti-HBs titers were significantly higher with CpG, for all time points after prime and boost (p<0.01) and a CpG dose response was evident. Cytotoxic T-lymphocyte response was greater in proportion and degree in CpG groups versus controls.

Conclusion: CpG 7909 may allow for 2-dose HBV vaccination. CTL enhancement with CpG may allow development of an effective therapeutic vaccine, and holds promise for its adjuvancy in HIV vaccine development.

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